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मानक

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“Step Out From the Old to the New”

IS 10121-1 (1982): Metal Bone Screws - Mechanical Requirements and Methods of Test, Part 1: Screws with Asymmetrical Thread, Variable Fitting (spherical), Stainless Steel [MHD 2: Orthopaedic Instruments, Implants and Accessories]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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Indian Standard



SPECIFICATION FOR
METAL BONE SCREWS — MECHANICAL
REQUIREMENTS AND METHODS OF TEST

PART I SCREWS WITH ASYMMETRICAL THREAD, VARIABLE
FITTING (SPHERICAL), STAINLESS STEEL

- 1. Scope** — Specifies the characteristics of, and corresponding mechanical test methods for metal bone screws used in surgery.
- 2. Material** — Bone screws conforming to this specification shall be manufactured from stainless steel, composition B, in accordance with IS : 5347-1969 'General requirements of metal surgical implants'.
- 3. Dimensions** — Each of the screws in the test sample shall conform to the dimensional requirements specified in IS : 9829 (Part I)-1981 'Specification for metal bone screws: Part I Screws with asymmetric thread, variable fitting (spherical)'.
- 4. Mechanical Properties** — Each of the screws in the test sample shall be tested for the minimum breaking torque and the minimum angle of rotation to failure (see 7). The minimum breaking torque and minimum angle of rotation to failure shall be as specified in Table 1.

TABLE 1 MECHANICAL PROPERTIES

Code and Diameter of Thread	Breaking Torque, <i>Min</i>	Angle of Rotation to Failure, <i>Min</i>
	N.m	Degree of Arc
HA 2.7	1.0	180
HA 3.5	2.3	180
HA 4.5	4.4	180
HB 4.0	1.3	90
HB 6.5	6.2	90

- 5. Surface Finish** — The surface of metal bone screws shall be free, when examined with the naked eye, of imperfections, such as nicks, scratches and other defects that would impair the serviceability of the screw. The final finish shall be continuous and free, when examined with the naked eye, of marks which are the results of previous operations such as grinding, polishing, burnishing, tumbling, etc.
- 6. Compliance and Retests** — Should any of the screws in the test sample not comply with any of the requirements, a further sample, comprising at least twice the number of screws of the original test sample, shall be taken from the lot in question and all tested as described above. Any failure amongst the second sample of screws shall constitute failure of the particular lot of screws to comply with this standard.

7. Determination of Breaking Torque and Angle of Rotation at Failure

- 7.1 Test Equipment** — The testing equipment shall satisfy the following:
- a) The maximum sensitivity on the lowest measuring range is not to be less than 0.01 N.m or its equivalent, and on other scales not less than 1 percent of full range deflection.
 - b) Selection of loading scale range, see 7.2.4.
 - c) The measuring device shall be capable of registering and indicating the reading of the maximum torque attained during the test.

- d) Unless the device, through which the torque is applied to the screw head, is capable of being clamped to prevent movement in the vertical direction, a device to prevent 'cam out' of the driver from the screw head should be incorporated into the system.
- e) The screw shall be clamped in such a manner as to prevent movement of the clamped portion of the screw and to ensure correct alignment.

7.2 Procedure

7.2.1 Insert the screw under test in the test block so that five full threads from the thread run-out are exposed. If less than five full threads are available, the results shall be accompanied by a statement of the precise test conditions.

7.2.2 Apply torque at a uniform rotational frequency within the range 1 to 5 r/min.

7.2.3 Load until fracture occurs and record the maximum torsional moment and the angle of rotation at failure.

7.2.4 Should the maximum torque recorded be less than 20 percent of the full range deflection of the scale, the test shall be repeated at a lower scale range.

7.3 Test Report — The test report shall include the following particulars:

- a) Reference to this Indian Standard;
- b) Maximum torsional moment, expressed to the nearest 0.1 N.m and given as the 'breaking torque'.
- c) Angle of rotation at failure, expressed to the nearest 10°.
- d) A statement of the precise test conditions if less than five full threads are exposed (see 7.2.1).

EXPLANATORY NOTE

This standard is based on ISO 6475/1-1980 (E) Implants for surgery-metal bone screws — Mechanical requirement and method of tests — Part I: Screws with asymmetrical thread, variable fitting (spherical), stainless steel, issued by the International Organization for Standardization (ISO).